

**WHAT IS CLAIMED IS:**

1           1.     A medical article sterilization device comprising:  
2                 a pretreatment area for medical articles, the pretreatment area having a heat  
3 source to heat the medical articles;  
4                 a device to form a housing in a first web;  
5                 an article loading station where a medical article heated in the pretreatment area  
6 is loaded into the housing in the first web;  
7                 an alignment device to align a second web with the first web; and  
8                 a sterilization-sealing station where the first web and the second web, with the  
9 medical article loaded into the housing are sterilized and then the first and second webs are  
10 sealed together.

1           2.     A medical article sterilization device according to claim 1, wherein the  
2 sterilization-sealing station further comprises gas injection pins to inject gas into the housing,  
3 between the first and second webs.

1           3.     A medical article sterilization device according to claim 2, wherein the  
2 sterilization-sealing station further comprises a steam source to inject steam into the housing,  
3 between the first and second webs.

1           4.     A medical article sterilization device according to claim 1, wherein the  
2 sterilization-sealing  
3 station further comprises a steam source to supply steam to the housing.

1           5.     A medical article sterilization device according to claim 1, wherein:  
2 substantially no moisture is supplied to the medical articles at the sterilization-  
3 sealing station, and  
4 the pretreatment area has a steam source to supply moisture to the medical  
5 articles.

1           6.     A medical article sterilization device according to claim 5, wherein:  
2 the sterilization-sealing station comprises a vacuum source and a controller,  
3 the vacuum source evacuates the housing,  
4 evacuating the housing removes moisture from the medical articles, and  
5 the controller maintains the pressure in the housing so as to allow some moisture  
6 to remain with the medical articles.

1           7.     A medical article sterilization device according to claim 6, wherein the  
2 controller maintains the pressure in the housing so as to allow the relative humidity in the  
3 housing to be at least 40 % during sterilization gas exposure.

1           8.     A medical article sterilization device comprising:

2 a device to form a housing in a first web;  
3 an article loading station where a medical article is loaded into the housing in  
4 the first web;  
5 an alignment device to align a second web with the first web; and  
6 a sterilization-sealing station where the first web and the second web, with the  
7 medical article loaded into the housing are sterilized and then, the first and second webs are  
8 sealed together, the sterilization-sealing station comprising gas injection pins to inject gas into  
9 the housing, between the first and second webs.

1 9. A medical article sterilization device according to claim 8, wherein the  
2 sterilization-sealing station further comprises a steam source to inject steam into the housing,  
3 between the first and second webs.

1 10. A medical article sterilization device according to claim 9, further comprising a  
2 pretreatment area for medical articles, the pretreatment area having a heat source to heat the  
3 medical articles.

1 11. A medical article sterilization device according to claim 8, wherein the second  
2 web is formed of a gas permeable material.

1 12. A medical article sterilization device according to claim 8, wherein:

2 substantially no moisture is supplied to the medical articles at the sterilization-  
3 sealing station, and

4 the medical article sterilization device further comprises a pretreatment area  
5 having a steam source to supply moisture to the medical articles.

1 13. A medical article sterilization device according to claim 12, wherein:  
2 the sterilization-sealing station further comprises a vacuum source and a  
3 controller,  
4 the vacuum source evacuates the housing,  
5 evacuating the housing removes moisture from the medical articles, and  
6 the controller maintains the pressure in the housing so as to allow some moisture  
7 to remain with the medical articles.

8 14. A medical article sterilization device according to claim 13, wherein the  
9 controller maintains the pressure in the housing so as to allow the relative humidity in the  
2 housing to be at least 40 % during sterilization gas exposure.

3 15 A method of sterilizing a medical article comprising:  
4 preheating a medical article in a pretreatment area;  
5 forming a housing in a first web;  
6 loading the medical article heated in the pretreatment area into the housing  
7 formed in the first web;

6 aligning a second web with the first web;  
7 sterilizing the medical article located in the housing and between the first and  
8 second webs;  
9 after sterilizing the medical article, sealing the first web to the second web, with  
10 the medical article located in the housing and between the first and second webs.

1 16. A method of sterilizing a medical article according to claim 15, further  
2 comprising injecting gas into the housing, between the first and second webs, through gas  
3 injection pins.

4 17. A method of sterilizing a medical article according to claim 16, wherein steam is  
5 injected into the housing, between the first and second webs, through the gas injection pins.

6 18. A method of sterilizing a medical article according to claim 15, wherein steam is  
7 injected into the housing, between the first and second webs.

8 19. A method of sterilizing a medical article according to claim 15, wherein:  
9 sterilization and sealing are conducted at a sterilization-sealing station,  
10 substantially no moisture is supplied to the medical article at the sterilization-  
11 sealing station, and  
12 steam is supplied to the medical article at the pretreatment area.

1           20.    A method of sterilizing a medical article according to claim 19, further  
2    comprising the steps of:  
3                evacuating the housing at the sterilization-sealing station so as to remove  
4    moisture from the medical article, and  
5                maintaining the pressure in the housing so as to allow some moisture to remain  
6    with the medical article.

1           21.    A medical article sterilization device according to claim 20, wherein the  
2    pressure in the housing is maintained so as to allow the relative humidity in the housing to be  
3    at least 40 % during sterilization gas exposure.

1           22.    A method of sterilizing a medical article comprising:  
2                forming a housing in a first web;  
3                loading a medical article into the housing formed in the first web;  
4                aligning a second web with the first web;  
5                injecting gas into the housing, between the first and second webs, through gas  
6    injection pins;  
7                sterilizing the medical article located in the housing and between the first and  
8    second webs; and  
9                after sterilizing the medical article, sealing the first web to the second web, with  
10   the medical article located in the housing and between the first and second webs.

1           23.    A method of sterilizing a medical article according to claim 22, wherein steam is  
2 injected into the housing, between the first and second webs, through the gas injection pins.

1           24.    A method of sterilizing a medical article according to claim 23, wherein the  
2 steam is injected into housing to pressurize the housing to a pressure of 60 to 100 psia.

1           25.    A method of sterilizing a medical article according to claim 24, wherein  
2 the housing is evacuated before pressurizing with steam, and  
3 the housing is evacuated after pressurizing with steam and then sterilizing gas is  
4 supplied to the housing.

1           26.    A method of sterilizing a medical article according to claim 24, wherein the  
2 housing is maintained in a condition pressurized with steam for a time period of 1 to 8 minutes.

1           27.    A method of sterilizing a medical article according to claim 24, wherein  
2 the housing is pressurized with steam and supplied with sterilizing gas within a  
3 form, fill and seal device having a sterilization-sealing station, which has an interior volume to  
4 contain the housing, and  
5 the housing is pressurized with steam to deliver 10 to 50 Btu of heat per cubic  
6 foot of interior volume.

1           28.    A method of sterilizing a medical article according to claim 22, wherein the  
2   second web is formed of a gas permeable material.

1           29.    A method of sterilizing a medical article according to claim 23, further  
2   comprising preheating the medical article in a pretreatment area.

1           30.    A method of sterilizing a medical article according to claim 22, wherein:  
2               sterilization and sealing are conducted at a sterilization-sealing station,  
3               substantially no moisture is supplied to the medical article at the sterilization-  
4   sealing station, and  
5               moisture is supplied to the medical article as steam at a pretreatment area.

1           31.    A method of sterilizing a medical article according to claim 30, further  
2   comprising the steps of:  
3               evacuating the housing at the sterilization-sealing station so as to remove  
4   moisture from the medical article, and  
5               maintaining the pressure in the housing so as to allow some moisture to remain  
6   with the medical article.

1           32.    A medical article sterilization device according to claim 31, wherein the  
2   pressure in the housing is maintained so as to allow the relative humidity in the housing to be  
3   at least 40 % during sterilization gas exposure.